# Terrestrial Animal Health Standards Commission Report

October 2008

CHAPTER 1.4.

## ANIMAL HEALTH SURVEILLANCE

Article 1.4.1.

## Introduction and objectives

- 1. In general, surveillance is aimed at demonstrating the absence of disease or infection, determining the occurrence or distribution of disease or infection, while also detecting as early as possible exotic or emerging diseases. The type of surveillance applied depends on the desired outputs needed to support decision-making. The following recommendations may be applied to all diseases, their agents and all susceptible species (including wildlife) as listed in the Terrestrial Code, and are designed to assist with the development of surveillance methodologies. Except where a specific surveillance method for a certain disease or infection is already described in the Terrestrial Code, the recommendations in this Chapter may be used to further refine the general approaches described for a specific disease or infection. Where detailed disease/infection-specific information is not available, suitable approaches should be based on the recommendations in this Chapter.
- 2. Animal health *surveillance* is an essential component necessary to detect *diseases*, to monitor disease trends, to control endemic and exotic diseases, to support claims for freedom from *disease* or *infection*, to provide data to support the *risk analysis* process, for both animal health and/or public health purposes, and to substantiate the rationale for sanitary measures. <u>Both domestic and wild animals are susceptible to certain *diseases/infections*. However, in the presence of appropriate biosecurity measures, *infection/disease* in wild animals does not imply that the same *infection/disease* is necessarily present in domestic animals in the same country or *zone*. *Surveillance* data underpin the quality of disease status reports and should satisfy information requirements for accurate *risk analysis* both for *international trade* as well as for national decision-making. Wildlife may be included because these can serve both as reservoirs and as sensitive indicators of important human and domestic animal *diseases*. Wildlife disease *surveillance* presents specific challenges that may differ importantly from disease *surveillance* in livestock.</u>
- 3. Essential prerequisites to enable an OIE Member to provide information for the evaluation of its animal health status are:
  - a) that the particular Member complies with the provisions of Chapter 3.1. of the *Terrestrial Code* on the quality and evaluation of the *Veterinary Services*;
  - b) that, where possible, *surveillance* data be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);

- c) that transparency in the planning and execution of *surveillance* activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1. of the *Terrestrial Code*.
- 4. The objectives of this Chapter are to:
  - a) provide guidance to the type of outputs that a surveillance system should generate;
  - b) provide recommendations to assess the quality of disease *surveillance* systems.

Article 1.4.2.

#### **Definitions**

The following definitions apply for the purposes of this Chapter:

Bias: A tendency of an estimate to deviate in one direction from a true value.

**Case definition:** A case definition is a set of criteria used to classify an *animal* or *epidemiological unit* as a *case*.

**Confidence:** In the context of demonstrating freedom from *infection*, confidence is the probability that the type of *surveillance* applied would detect the presence of *infection* if the population were infected. The confidence depends on, among other parameters, the assumed level of *infection* in an infected population. The term refers to confidence in the ability of the *surveillance* applied to detect *disease*, and is equivalent to the sensitivity of the *surveillance* system.

**Early detection system:** A system for the timely detection and identification of an incursion or emergence of *disease/infection* in a country, *zone* or *compartment*. An early detection system should be under the control of the *Veterinary Services* and should include the following characteristics:

- a) representative coverage of target animal populations by field services;
- b) ability to undertake effective *disease* investigation and reporting;
- c) access to *laboratories* capable of diagnosing and differentiating relevant *diseases*;
- d) a training programme for *veterinarians*, *veterinary para-professionals* and others involved in handling *animals* for detecting and reporting unusual animal health incidents;
- e) the legal obligation of private veterinarians in relation to the Veterinary Authority;
- f) timely reporting system of the event to the Veterinary Services;
- g) a national chain of command.

**Outbreak definition:** An outbreak definition is a set of criteria used to classify the occurrence of one or more *cases* in a group of *animals* or units as an *outbreak*.

**Probability sampling:** A sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

**Sample:** The group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide *surveillance* information.

**Sampling units:** The unit that is sampled, either in a random survey or in non-random *surveillance*. This may be an individual *animal* or a group of *animals* (e.g. an *epidemiological unit*). Together, they comprise the sampling frame.

Sensitivity: The proportion of truly positive units that are correctly identified as positive by a test.

**Specificity:** The proportion of truly negative units that are correctly identified as negative by a test.

**Study population:** The population from which *surveillance* data are derived. This may be the same as the target population or a subset of it.

**Surveillance:** The systematic ongoing collection, collation, and analysis of data, and the timely dissemination of information to those who need to know so that action can be taken.

**Surveillance system:** A method of *surveillance* that may involve one or more component activities that generates information on the health, disease or zoonosis status of animal populations.

**Survey:** An investigation in which information is systematically collected, usually carried out on a sample of a defined population group, within a defined time period.

**Target population:** The population about which conclusions are to be inferred.

**Test:** A procedure used to classify a unit as either positive, negative or suspect with respect to an *infection* or *disease*.

**Test system:** A combination of multiple tests and rules of interpretation which are used for the same purpose as a test.

Wildlife: Mammals and birds which are not permanently captive or owned free-range. This definition includes the categories of "wild animal" (wild animal genotype living outside of controlling human influence) and "feral animal" (domestic animal genotype living outside of controlling human influence).

Article 1.4.3.

## Principles of surveillance

#### 1. Types of surveillance

- a) Surveillance may be based on many different data sources and can be classified in a number of ways, including:
  - i) the means by which data are collected (active versus passive *surveillance*);
  - ii) the disease focus (pathogen-specific versus general surveillance); and

- iii) the way in which units for observation are selected (structured surveys versus non-random data sources).
- b) In this Chapter, *surveillance* activities are classified as being based on:

#### **EITHER**

- i) structured population-based surveys, such as:
  - systematic sampling at *slaughter*,
  - random surveys;

## OR

- ii) structured non-random surveillance activities, such as:
  - disease reporting or notifications;
  - control programmes/health schemes;
  - targeted testing/screening;
  - ante-mortem and post-mortem inspections;
  - laboratory investigation records;
  - biological specimen banks;
  - sentinel units;
  - field observations;
  - farm production records;
  - wildlife disease data.
- c) In addition, all available surveillance data should be supported by related information, such as:
  - i) data on the epidemiology of the *infection*, including environmental, host population distribution, and climatic information;
  - ii) data on animal movements and <u>including transhumance</u>, and <u>natural wildlife</u> <u>migrations</u>;
  - iii) trading patterns for animals and animal products;
  - <u>iiiiv</u>) national animal health regulations, including information on compliance with them and their effectiveness;
  - ivy) history of imports of potentially infected material; and
  - <u>vvi</u>) biosecurity measures in place.

d) The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

#### 2. Critical elements

In assessing the quality of a *surveillance* system, the following critical elements need to be addressed over and above quality of *Veterinary Services* (Chapter 3.1.).

## a) Populations

Ideally, *surveillance* should be carried out in such a way as to take into account all animal species susceptible to the *infection* in a country, *zone* or *compartment*. The *surveillance* activity may cover all individuals in the population or part of them. When *surveillance* is conducted only on a *subpopulation*, care should be taken regarding the inferences made from the results.

Definitions of appropriate populations should be based on the specific recommendations of the disease Chapters of the *Terrestrial Code*.

## b) Epidemiological unit

The relevant *epidemiological unit* for the *surveillance* system should be defined and documented to ensure that it is representative of the population. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.

## c) Clustering

Infection in a country, zone or compartment usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of infected animals within a herd, a cluster of pens in a building, or a cluster of farms in a compartment). Clustering should be taken into account in the design of surveillance activities and the statistical analysis of surveillance data, at least at what is judged to be the most significant level of clustering for the particular animal population and infection.

#### d) Case and outbreak definitions

Clear and unambiguous case and outbreak definitions should be developed and documented for each pathogen under *surveillance*, using, where they exist, the standards in the *Terrestrial Code*. For wildlife disease *surveillance*, it is essential to correctly identify and report host animal taxonomy (including genus and species).

#### e) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of *surveillance* data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different

methodologies may be needed to accommodate the relevant <u>host species</u>, pathogens, varying production and *surveillance* systems, and types and amounts of data and information available.

The methodology used should be based on the best available information that is in accord with current scientific thinking. The methodology should be in accordance with this Chapter and fully documented, and supported by reference to the scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

## f) Testing

Surveillance involves the detection of disease or infection by the use of appropriate case definitions based on the results of one or more tests for evidence of infection or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity and predictive values. Imperfect sensitivity and/or specificity will have an impact on the conclusions from surveillance. Therefore, these parameters should be taken into account in the design of surveillance systems and analysis of surveillance data.

The values of sensitivity and specificity for the tests used should be specified, and the method used to determine or estimate these values should be documented. Alternatively, where values for sensitivity and/or specificity for a particular test are specified in the *Terrestrial Manual*, these values may be used as a guide. For each host species to which a diagnostic test is applied, whenever possible, the tests should be shown to have acceptable sensitivity and specificity for that particular host species.

Samples from a number of *animals* or units may be pooled and subjected to a testing protocol. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

## g) Quality assurance

Surveillance systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

#### h) Validation

Results from animal health *surveillance* systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

## i) Data collection and management

The success of a *surveillance* system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis, is critical. Factors influencing the quality of collected data include:

- the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location; this requires effective collaboration among all stakeholders, such as government ministries, non-governmental agencies, and others, particularly for data involving wildlife;
- the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;
- maintenance of disaggregated data rather than the compilation summary data;
- minimisation of transcription errors during data processing and communication.

Article 1.4.4.

## Structured population-based surveys

In addition to the principles for *surveillance* discussed above, the following recommendations should be used when planning, implementing and analysing surveys.

## 1. Types of surveys

Surveys may be conducted on the entire target population (i.e. a census) or on a sample. A sample may be selected in either of the two following ways:

- a) non-probability based sampling methods, such as:
  - i) convenience;
  - ii) expert choice;
  - iii) quota;
- b) probability based sampling methods, such as:
  - i) simple random selection;
  - ii) cluster sampling;
  - iii) stratified sampling;
  - iv) systematic sampling.

Non-probability based sampling methods will not be discussed further.

Periodic or repeated surveys conducted in order to document *disease* freedom should be done using probability based sampling methods so that data from the study population can be extrapolated to the target population in a statistically valid manner.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be made of any biases that may be inherent in the survey design.

## 2. Survey design

The population of *epidemiological units* should first be clearly defined; hereafter sampling units appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size and structure of the population being studied, the epidemiology of the *infection* and the resources available.

Data on wild animal population size often do not exist and should be determined before a survey can be designed. The expertise of wildlife biologists may be sought in the gathering and interpretation of such population data. Historical population data should be updated since these may not reflect current populations.

## 3. Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the object of the study such as the presence or absence of *infection*. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems. In order to detect the presence of an *infection* in a population of unknown disease status, targeted sampling methods that optimise the detection of *infection* can be used. In such cases, care should be taken regarding the inferences made from the results.

## 4. <u>Sampling methods</u>

When selecting *epidemiological units* from within a population, probability sampling (e.g. simple random selection) should be used. When this is not possible, sampling should provide the best practical chance of generating a sample that is representative of the target population.

In any case, the sampling method used at all stages should be fully documented and justified.

## 5. Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. *infection*) or to estimate a parameter (e.g. the prevalence of *infection*). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

#### Article 1.4.5.

#### Structured non-random surveillance

Surveillance systems routinely use structured non-random data, either alone or in combination with surveys.

#### 1. Common non-random surveillance sources

A wide variety of non-random *surveillance* sources may be available. These vary in their primary purpose and the type of *surveillance* information they are able to provide. Some *surveillance* systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from *infection*. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data (e.g. disease reporting systems, sentinel sites, testing schemes). *Surveillance* systems routinely use structured non-random data, either alone or in combination with surveys.

## a) Disease reporting or notification systems

Data derived from *disease* reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for *risk analysis*, or for early detection. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a high specificity. Reports should be released by the laboratory in a timely manner, with the amount of time from *disease* detection to report generation minimized (to hours in the case of introduction of a foreign animal disease).

Whenever the responsibility for disease notification falls outside the scope of the *Veterinary* Authority, for example for diseases in wildlife, effective communication and data sharing should be established with the relevant authorities to ensure comprehensive and timely disease reporting.

## b) Control programmes / health schemes

Animal disease control programmes or health schemes, while focusing on the control or eradication of specific diseases, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured surveillance.

## c) Targeted testing / screening

This may involve testing targeted to selected sections of the population (subpopulations), in which *disease* is more likely to be introduced or found. Examples include testing culled and dead *animals*, swill fed *animals*, those exhibiting clinical signs, *animals* located in a defined geographic area and specific age or commodity group.

#### d) Ante-mortem and post-mortem inspections

Inspections of animals at abattoirs may provide valuable surreillance data. The sensitivity and specificity of the particular slaughterhouse inspection system for detecting the presence of infectious agents of surveillance interest under the particular inspection arrangements applying in a country should be pre-determined by the Competent Authority if the data is to

be fully utilised. The accuracy of the inspection system will be influenced by:

- i) the level of training and experience of the staff doing the inspections, and the ratio of staff of different levels of training;
- ii) the involvement of the *Competent Authorities* in the supervision of ante-mortem and post-mortem inspections;
- iii) the quality of construction of the *abattoir*, speed of the slaughter chain, lighting quality, etc.; and
- iv) staff morale/motivation for accurate and efficient performance.

Abattoir inspections are likely to provide good coverage only for particular age groups and geographical areas. Abattoir surveillance data are subject to obvious biases in relation to target and study populations (e.g. only animals of a particular class and age may be slaughtered for human consumption in significant numbers). Such biases need to be recognized when analysing surveillance data.

Both for traceback in the event of detection of *disease* and for analysis of spatial and *berd*-level coverage, there should be, if possible, an effective identification system that relates each *animal* in the *abattoir* to its locality of origin.

## e) Laboratory investigation records

Analysis of laboratory investigation records may provide useful *surveillance* information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardized methods for interpretation and data recording. As with *abattoir* inspections, there needs to be a mechanism to relate specimens to the farm of origin.

#### f) Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection*, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

#### g) Sentinel units

Sentinel units/sites involve the identification and regular testing of one or more of *animals* of known health/immune status in a specified geographical location to detect the occurrence of *disease* (usually serologically). They are particularly useful for *surveillance* of *diseases* with a strong spatial component, such as vector-borne *diseases*. Sentinel units provide the opportunity to target *surveillance* depending on the likelihood of *infection* (related to vector habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from *infection*, or provide data on prevalence and incidence as well as the distribution of *disease*.

#### h) Field observations

Clinical observations of *animals* in the field are an important source of *surveillance* data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear, unambiguous and easy to apply standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

## i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of *disease* at the *herd* or *flock* level. In general, the sensitivity of this approach may be quite high (depending on the *disease*), but the specificity is often quite low.

## <u>i)</u> Wildlife data

Specimens from wild animals for disease *surveillance* may be available from sources such as hunters and trappers, road-kills, wild animal meat markets, sanitary inspection of hunted animals,-morbidity and mortality observations by the general public, wildlife rehabilitation centres, wildlife biologists and wildlife agency field personnel, farmers and other landholders, naturalists and conservationists. Wildlife data such as census data, trends over time, and reproductive success can be used in a manner similar to farm production records for epidemiological purposes.

## 2. Critical elements for structured non-random surveillance

There is a number of critical factors which should be taken into account when using structured non-random *surveillance* data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. *Surveillance* data from non-random data sources may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

## 3. Analytical methodologies

Different methodologies may be used for the analysis of non-random surveillance data.

Different scientifically valid methodologies may be used for the analysis of non-random *surveillance* data. Where no data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.

## 4. Combination of multiple sources of data

The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented including references to published material.

Surveillance information gathered from the same country, zone or compartment at different times may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. For instance, repeated annual surveys may be analysed to provide a cumulative level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-

random sources, may be able to achieve the same level of confidence in just one year.

Analysis of *surveillance* information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account. The sensitivity, specificity and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

#### Article 1.4.6.

## Surveillance to demonstrate freedom from disease/infection

1. Requirements to declare a country, zone or compartment free from disease/infection without pathogen specific surveillance

This Article provides general principles for declaring a country, zone or compartment free from disease/infection in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this Article are based on the principles described in Article 1.4.3. of this Chapter and the following premises:

- in the absence of *disease* and vaccination, the animal population would become susceptible over a period of time;
- the disease agents to which these provisions apply are likely to produce identifiable clinical signs in susceptible *animals*;
- competent and effective *Veterinary Services* will be able to investigate, diagnose and report disease, if present;
- <u>diseases/infections</u> can affect both wild and domestic animals;
- the absence of *disease/infection* over a long period of time in a susceptible population can be substantiated by effective disease investigation and reporting by a Member.
- a) Historically free

Unless otherwise specified in the relevant *disease* Chapter, a country, *zone* or *compartment* may be recognised free from *infection* without formally applying a pathogen-specific *surveillance* programme when:

- i) there has never been occurrence of disease, or
- ii) eradication has been achieved or the *disease/infection* has ceased to occur for at least 25 years, provided that for at least the past 10 years:
- iii) it has been a notifiable disease;
- iv) an early detection system has been in place for all relevant species;
- v) measures to prevent *disease/infection* introduction have been in place; no vaccination against the *disease* has been carried out unless otherwise provided in the *Terrestrial Code*;

vi) infection is not known to be established in wildlife within the country or zone intended to be declared free. (A country or zone cannot apply for historical freedom if there is any evidence of infection in wildlife. However, specific surveillance in wildlife is not necessary.)

## b) Last occurrence within the previous 25 years

Countries, *zones* or *compartments* that have achieved eradication (or in which the *disease/infection* has ceased to occur) within the previous 25 years, should follow the pathogen-specific *surveillance* requirements in the *Terrestrial Code* if they exist. In the absence of specific requirements for *surveillance* in the *Terrestrial Code*, countries should follow the general recommendations on *surveillance* to demonstrate animal health status outlined in this Chapter provided that for at least the past 10 years:

- i) it has been a notifiable disease;
- ii) an early detection system has been in place;
- iii) measures to prevent disease/infection introduction have been in place;
- iv) no vaccination against the *disease* has been carried out unless otherwise provided in the *Terrestrial Code*;
- v) infection is not known to be established in wildlife within the country or zone intended to be declared free. (A country or zone cannot apply for freedom if there is any evidence of infection in wildlife. However, specific surveillance in wildlife is not necessary.)

## 2. Recommendations for the discontinuation of pathogen-specific screening after recognition of freedom from infection

A country, zone or compartment that has been recognised as free from infection following the provisions of the Terrestrial Code may discontinue pathogen-specific screening while maintaining the infection-free status provided that:

- a) it is a notifiable disease;
- b) an early detection system is in place;
- c) measures to prevent *disease/infection* introduction are in place;
- d) vaccination against the *disease* is not applied;
- e) infection is known not to be established in wildlife. (Specific surreillance in wildlife has demonstrated the absence of infection. It can be difficult to collect sufficient epidemiological data to prove absence of infection in wild animal populations. Therefore, a wide range of supporting evidence should be used to make this assessment.)

## 3. <u>International recognition of disease/infection free status</u>

For diseases for which procedures exist whereby the OIE can officially recognise the existence of a disease/infection free country, zone or compartment, a Member wishing to apply for recognition of

this status shall, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country, *zone* or *compartment* concerned. Such documentation should be presented according to the recommendations prescribed by the OIE for the appropriate animal *diseases*.

## 4. Demonstration of freedom from infection

A *surveillance* system to demonstrate freedom from *infection* should meet the following requirements in addition to the general requirements for *surveillance* outlined in Article 1.4.3. of this Chapter.

Freedom from *infection* implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *infection*.

Demonstrating freedom from *infection* involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Members) that *infection* with a specified pathogen is not present in a population. In practice, it is not possible to prove (i.e., be 100% confident) that a population is free from *infection* (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that *infection*, if present, is present in less than a specified proportion of the population.

However, finding evidence of *infection* at any level in the target population automatically invalidates any freedom from *infection* claim unless otherwise stated in the relevant *disease* Chapter. The implications of *disease/infection* in wildlife for the status of domestic animals in the same country or *zone* should be assessed in each situation, as indicated in the relevant Chapter on each *disease* in the *Terrestrial Code*).

Evidence from targeted, random or non-random data sources, as stated before, may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

Article 1.4.7.

#### Surveillance for distribution and occurrence of infection

Surveillance to determine distribution and occurrence of infection or of other relevant health related events is widely used to assess progress in the control or eradication of selected diseases and pathogens and as an aid to decision making. It has, however, relevance for the international movement of animals and products when movement occurs among infected countries.

In contrast to *surveillance* to demonstrate freedom from *infection*, *surveillance* used to assess progress in control or eradication of selected *diseases* and pathogens is usually designed to collect data about a number of variables of animal health relevance, for example:

- 1. prevalence or incidence of *infection*;
- 2. morbidity and mortality rates;
- 3. frequency of disease/infection risk factors and their quantification;
- 4. frequency distribution of *herd* sizes or the sizes of other *epidemiological units*;

- 5. frequency distribution of antibody titres;
- 6. proportion of immunised animals after a vaccination campaign;
- 7. frequency distribution of the number of days elapsing between suspicion of *infection* and *laboratory* confirmation of the diagnosis and/or to the adoption of control measures;
- 8. farm production records, etc.
- 9. Role of wildlife in maintenance or transmission of the infection.